DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

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July 16, 1999

WARNING LETTER
CHI-29-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dominic P. Stramaglia, President
Supreme Lobster & Seafood Co.
220 E. North Ave.
Villa Park, IL 60181

Dear Mr. Stramaglia:

On March 31 and April 1, 7 and 9, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant as a follow-up to our inspection in December 1998, and subsequent letter to you dated February 18, 1999. The inspection and letter evaluated and discussed your compliance with the new FDA Hazard Analysis Critical Control Point (HACCP) regulations. This FDA inspection was made again to evaluate HACCP requirements. At the conclusion of the inspection, you were presented with Form FDA-483, List of Observations, and Form FD-3501, Domestic Seafood HACCP Report. The reports describe deviations to FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for Human Food (21 CFR 110). By virtue of these violations, the seafood products processed at your facility at 220 E. North Ave., Villa Park, Illinois, are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigators found the following violations:

- Failure to implement adequate monitoring procedures for scombrotoxin forming species, i.e., your records fail to identify the adequacy of ice coverage for these fish in storage. The investigators observed uncovered and uniced yellow-fin tuna in storage on March 31 and again on April 1. There was no record to indicate failure of this critical limit (CL) or that any corrective action was taken to remedy this critical failure.

- Failure to list appropriate CLs in a HACCP plan as required by 21 CFR Section 123.6(c)(3). Your HACCP plan for scombroid toxin forming species (scombroid fish), which includes tuna, has a CL temperature of not to exceed 45°F in finished product cooler storage and in your shipping trucks. The temperature 45°F is not appropriate for storage of histamine producing species from the current science to our knowledge. The 45°F is considered a moderate abuse temperature in scombroid fish, and is higher than the recommended CL storage temperature (40°F) to properly control histamine formation in this species.

Therefore, exposure of scombroid fish to temperatures above 40°F must be for limited duration, i.e., fresh unfrozen scombroid fish should not be exposed to temperatures above 40°F [but below 70°F] for more than eight hours, cumulatively, before cooking or final freezing, or above 70°F form more than four hours cumulatively, before cooking or final freezing.

- Monitoring record data was missing initially, and when entered, may not have been the actual values observed. Please refer to the FDA-483 (attached) items #3 and #4 on page one, describing these observations.

Also, the marketing of lobsters which you identify as "stills" is a violation of Section 402(a)(5) of the Act which states that food is adulterated if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter.

The violations cited are not all inclusive since not every product could be evaluated at the time. It is your responsibility to evaluate your program and ensure it is in compliance with the regulations. You should take prompt action to correct these violations. Although improvements were reported, we are concerned that many substantial violations were found to continue since the inspection in December 1998, and subsequent letter of February 18, 1999. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. We are also providing firm's the opportunity to take a HACCP refresher course to assist in better understanding and working with the Seafood HACCP program. Please contact the local FDA office for further information. If you enroll in one of these courses, we will extend your response time or further regulatory action provided products are not critically compromised resulting in a danger to health.

In addition, the following deviations were observed:

- Failure to prepare and implement a HACCP plan to control a food safety hazard (metal) that is reasonably likely to occur, i.e., there is no written HACCP plan for processing frozen Alaskan king crab legs that are cut and split with a metal band saw.

- Failure to prepare and implement a HACCP plan to control a food safety hazard that is reasonably likely to occur, i.e., there is no written HACCP plan to monitor and record sanitation conditions and corrective actions (Reference - 21 CFR Section 123.11 and Part 110). These violations were in areas of concern as follows:

  Safety of water for processing. This area is not addressed or monitored in your SSOP.
  Prevention of cross contamination (Refer to FDA-483 page 2, items 3 and 4).
  Protection from adulteration (Refer to FDA-483 page 2, items 1 and 2).
  Proper labeling, storage and use of toxic compounds (Refer to FDA-483 item 5).

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Paul Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,

/s/
Raymond V. Mlecko
District Director